(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 July 2001 (05.07.2001)

PCT

(10) International Publication Number
WO 01/47581 A1

(51) International Patent Classification[7]: A61M 1/36

(21) International Application Number: PCT/IB00/01954

(22) International Filing Date:
22 December 2000 (22.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
TO99A001165 28 December 1999 (28.12.1999) IT

(71) Applicant *(for all designated States except US)*: **HOSPAL AG** [CH/CH]; Dornacherstrasse 8, CH-4008 Basel (CH).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GIACOMELLI, Sara** [IT/IT]; Via Matteotti, 8, I-46025 Poggio Rusco (IT). **ROSSI, Ivan** [IT/IT]; Via Matteotti, 8, I-46025 Poggio Rusco (IT). **CANINI, Enrico** [IT/IT]; Via A. Baraldini 14/A, I-41037 Moritizzuolo, Mirandola (Mo) (IT).

(74) Agent: **LEJEUNE, Daniel**; Hospal Service Brevets, 61, avenue Tony Garnier, F-69007 Lyon (FR).

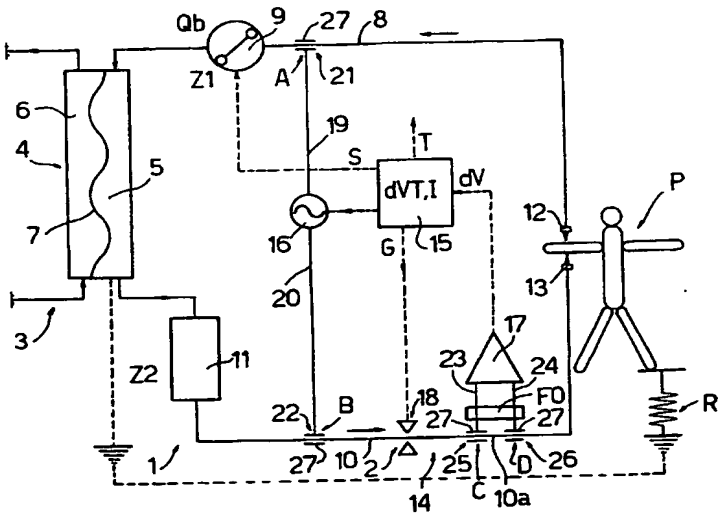
(81) Designated States *(national)*: AU, CA, JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND DEVICE FOR MONITORING THE ACCESS TO THE CARDIOVASCULAR SYSTEM OF A PATIENT



(57) Abstract: A device for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood in a machine (1) comprising a treatment device (4) and an extracorporeal circuit (2), comprises: a voltage generator (16) for generating a potential difference between a part of the machine (1) and a first point (B) of a venous branch (8) of the extracorporeal circuit (2), connecting the patient to the treatment device (4); a detector (17) for detecting the value (dV) of a quantity that correlates with the electric current along at least one section (10a; 10b; 10c) of the venous branch (10) between the first point (B) and a venous needle (13) fitted at the end of the venous branch (8) and inserted in the vascular system of the patient (P); calculating means (15) for comparing the detected value (dV) with a reference range (I).

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METHOD AND DEVICE FOR MONITORING THE ACCESS TO THE CARDIOVASCULAR SYSTEM OF A PATIENT

The present invention relates to a method and a device for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood.

The invention is useful in any kind of treatment in which blood is continuously withdrawn from a patient, circulated and treated in a treatment device, and returned, once treated, to the patient. Hemodialysis, hemofiltration, apheresis and plasmapheresis are examples of such treatment.

For the sake of clarity, the invention will be described hereunder in relation to a specific treatment, hemodialysis, to which however it is not limited as will readily appear to the persons skilled in the art.

A dialysis machine generally comprises.

- a filter (hemodialyzer) having a first and a second compartments separated from one another by a semipermeable membrane;
- an extracorporeal blood circuit, having an arterial branch connected to an inlet of the first compartment and a venous branch connected to an outlet of the first compartment; a blood pump is arranged on the arterial line and a bubble trap is connected to the venous line;
- an dialysis liquid circuit, having an fresh dialysis liquid supply branch connected to an inlet of the second compartment and a used liquid branch connected to an outlet of the second compartment.

In use, the blood of the patient and the dialysis liquid are respectively circulated in the first and the second compartments, generally in counterflow.

During a dialysis treatment, undesirable substances (by-products of the metabolism, such as urea, creatinine, etc.) contained in the blood migrate across the semipermeable membrane from the blood

compartment to the dialysis liquid compartment by diffusion (dialysis phenomenon, strictly speaking) and also generally by convection, a fraction of plasma water being usually filtered during the treatment so that the patient looses a few kilograms (so-called "weight loss") corresponding to an excess of water accumulated in the body between two treatment sessions.

Each branch of the extracorporeal circuit is fitted with a needle (respectively, arterial needle and venous needle), by means of which the extracorporeal circuit is connected to the patient: just before starting the treatment, the arterial needle and the venous needle are inserted in the fistula of the patient (portion of a vein surgically connected to an artery) for respectively collecting the blood to be treated and returning the treated blood to the patient's cardiovascular system.

Disconnection of one of the aforementioned needles from the fistula causes interruption of access to the patient's cardiovascular system. Disconnection of the venous needle, if not detected in time, has particularly serious consequences, as it can cause exsanguination of the patient. For this reason there have been various attempts to provide methods capable of detecting disconnection of the needles, and especially of the venous needle.

One of these methods, which is based on the electrical conductivity of the blood, is described in WO 99/12588. According to this method, the extracorporeal circuit and the patient's cardiovascular system are subjected to an electric current, and changes in the current that are caused by the disconnection of one of the needles or both of the needles is detected, by means of measuring instruments arranged along the extracorporeal circuit. The measuring instrument used are inductive couplers, i.e. coils arranged at predetermined locations along the extracorporeal blood circuit.

The method described above has various drawbacks. In particular, although valid from the theoretical standpoint, this method is not able to provide satisfactory results from the practical standpoint, because the high electrical impedance caused by the peristaltic pump, which in fact interrupts the continuity of blood flow, necessitates operating with relatively high currents in order to make use of the scant conductivity of the materials of which the extracorporeal circuit, the dialyzer, the hose of the peristaltic pump and the bubble trap are made (PVC, polycarbonate). The use of relatively high currents is certainly not advisable in a machine connected to a patient and even if they were used, it would not be possible to transmit these high currents by means of an inductive coupler which, among other things, also generates parasitic currents which disturb the measurement. In some dialysis machines the bubble trap also represents a high impedance of the same order of magnitude as the peristaltic pump, and thus makes one of the drawbacks previously described even more acute.

Therefore, in view of the fact that it is advisable to operate with relatively low currents and that the impedance of the peristaltic pump, and in the majority of cases, of the bubble trap, is high, it follows that disconnection of one of the needles causes only slight changes in current, such as could be confused with the background noise of the measuring instrument.

Furthermore, this method does not take into account that the patient might be connected to earth and that the dialyzer itself is in fact connected to earth, since the dialysis fluid circuit is connected to earth in accordance with the provisions of the safety standards relating to dialysis machines.

The aim of the present invention is to provide a method that obviates the drawbacks of the prior art.

According to the present invention, a method is provided for monitoring the access to the

cardiovascular system of a patient undergoing an extracorporeal treatment of blood in a machine comprising a treatment device and an extracorporeal circuit having an arterial branch and a venous branch, the arterial branch having a first end fitted with an arterial needle to be inserted in the vascular system of the patient and a second end connected to an inlet of the treatment device, and the venous branch having a first end connected to an outlet of the treatment device and a second end fitted with an venous needle to be inserted in the vascular system of the patient,
the method being characterized in that it comprises the steps of:

- generating a potential difference between a first point of the venous branch and a part of the machine;
- detecting the value (dV) of a quantity that correlates with the electric current along at least one section of the venous branch between the first point (B) and the venous needle; and
- comparing the detected value (dV) with a reference range (I).

The present invention relates, in addition, to a monitoring device.

According to the present invention, a device is provided for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood in a machine comprising a treatment device and an extracorporeal circuit having an arterial branch and a venous branch, the arterial branch having a first end fitted with an arterial needle to be inserted in the vascular system of the patient and a second end connected to an inlet of the treatment device, and the venous branch having a first end connected to an outlet of the treatment device and a second end fitted with an venous needle to be inserted in the vascular system of the patient,
the device being characterized in that it comprises:

- a voltage generator for generating a potential difference between a first point (B) of the venous branch and a part of the machine;
- a detector for detecting the value (dV) of a quantity that correlates with the electric current along at least one section of the venous branch between the first point (B) and the venous needle;
- calculating means for comparing the detected value (dV) with a reference range (I).

The invention will now be described, with respect to the appended drawings, in which:

- Fig. 1 is a schematic representation of a dialysis machine connected to a patient and equipped with a monitoring device according to the invention;
- Fig. 2 is a schematic representation of a dialysis machine connected to a patient and equipped with a variant of the device in Fig. 1; and
- Fig. 3 is a schematic representation of a dialysis machine connected to a patient and equipped with another variant of the device in Fig. 1.

In Figs. 1, 2 and 3, the number 1 indicates a dialysis machine connected to a patient P. The machine 1 comprises an extracorporeal blood circuit 2 and a dialysis fluid circuit 3 which pass through a dialyzer 4, which comprises a blood compartment 5 and a dialysis compartment 6 separated by a semipermeable membrane 7.

The extracorporeal blood circuit 2 comprises, in addition to the compartment 5 of dialyzer 4, an arterial branch 8, along which a peristaltic pump 9 is arranged, supplying a blood flow Q_b, and a venous branch 10, to which a bubble trap 11 is connected. Arterial branch 8 has a needle 12 which, in use, is inserted in a fistula of patient P to collect blood from the cardiovascular system of the patient P, while venous branch 10 has a venous needle 13 which, in use, is inserted in the fistula for returning the treated blood to the cardiovascular system of patient P. Arterial and venous branches 8 and 10 are tubes made of a plastic material, generally PVC, as well as bubble trap 11.

Dialyzer 4 is also made of plastic material, the housing of it generally of polycarbonate.

In Figs. 1, 2 and 3, machine 1 is equipped with a device 14 for detecting disconnection of needles 12 and 13. The principle of the device 14 is based on the electrical conductivity of the blood and on data found experimentally that showed that circuit 2 made of PVC can be regarded as an insulator and that both the peristaltic pump 9 and the bubble trap 11 can be regarded as concentrated impedances designated Z1 and Z2 respectively. Peristaltic pump 9 cyclically interrupts the blood flow Q_b, at each half-turn of the pump 9 and accordingly the impedance Z1 is a function of the number of turns of pump 9 and of the supply frequency. Experiments have established that the impedance Z1 is between 500 and 2000 kΩ. The impedance Z2 is determined as well by the fact that the blood flow Q_b is interrupted in the bubble trap 11 and the value assumed by Z2 is also between 500 and 2000 kΩ. Recent designs of bubble trap have a relatively low impedance, which is negligible with respect to the impedance Z1. This circumstance will be borne in mind when describing the operation of device 14.

The impedances of the other components of extracorporeal circuit 2 are negligible with respect to the values of impedance Z1. To evaluate the operation of device 14, it is necessary to bear in mind that the dialyzer 4 is connected to earth via the dialysis fluid circuit 3 and that the patient P may be connected to earth (R = 0) or insulated (R = infinity) or in a situation intermediate between the two preceding limiting situations. These distinctions are important as it would be difficult to prevent the patient P from moving, for example resting a foot on the floor or placing a hand on the bedhead of an uninsulated bed, thus altering the configuration of the possible electric circuits defined by the machine 1, the patient P, and device 14.

In Fig. 1, device 14 comprises a control unit 15, a generator 16 connected to arterial and venous branches 8 and 10, a detector 17 of a voltage drop and a clamp 18 arranged along venous branch 10. Generator 16 is connected respectively by two conductors 19 and 20 and by two capacitive couplers 21 and 22 respectively to arterial branch 8 and to venous branch 10. Detector 17 is connected by two conductors 23 and 24 and by two capacitive couplers 25 and 26 to venous branch 10 for detecting the voltage drop along a predetermined section 10a of branch 10. An optimum filter FO is arranged along conductors 23 and 24 for minimizing the effect of noise on the input of detector 17, which is connected to control unit 15 for transmitting a value dV indicating the voltage drop in section 10a to unit 15, which compares this value with a threshold value dVT. If the value detected is not inside a range I around the threshold value dVT, control unit 15 emits a control signal S for stopping pump 9, a control signal G for closing clamp 18 and a signal T for emitting a visible and/or acoustic alarm signal.

Capacitive couplers 21, 22, 25 and 26 are made with respective metal tubes 27, which are connected to the respective conductors 19, 20, 23 and 24 and are arranged around portions of the respective PVC tubes. From the electrical standpoint, tube 27 defines a first plate of a capacitor, the PVC tube defines the dielectric, and the blood inside the PVC tube defines the second plate.

Capacitive coupler 21 is arranged on arterial branch 8 at a point A between the arterial needle 12 and the peristaltic pump 9, while capacitive coupling 22 is arranged on the arterial branch 10 at point B between bubble trap 11 and needle 13. Detector 17 is connected to venous branch 10 at points C and D, both of which are between point B and the venous needle 13 and define the end of section 10a.

When the patient is insulated (R infinite) and impedance Z2 is high, the operation of the monitoring device 14 according to the invention is as follows: the blood being circulated in the extracorporeal circuit 2 in the direction indicated by the arrows in Fig. 1, a potential difference is applied between venous branch 10 and arterial branch 8 by means of generator 16 and the respective capacitive couplers 21 and 22. This potential difference generates a current between a section of venous branch 10 and a section of arterial branch 8 which is closed by the cardiovascular system of the patient P on account of the high impedances Z1 and Z2 on the other portion of circuit 2. Detector 17 detects the voltage drop along section 10a of arterial branch 10 and stores a value indicating the voltage drop as threshold value dVT, determines the range I of acceptability around the threshold value dVT and checks whether the successive values dV are inside range I.

When one of the needles 12 and 13 accidentally becomes disconnected from the fistula, the detector 17 detects the cancellation of the voltage drop dV in section 10a, and the control unit 15 emits signals S, G and T for stopping the peristaltic pump 9, closing the clamp 18, and emitting an alarm signal.

The monitoring device 14 is particularly advantageous because it by-passes the impedances Z1 and Z2, and the dialyzer 4 which is connected to earth. Therefore it is possible to work with relatively low currents since disconnection of one of the needles 12 and 13 represents an appreciable change in the current along a circuit comprising a portion of the arterial branch 8 and a portion of the venous branch 10, the conductors 19 and 20 and the cardiovascular system of the patient P.

When the patient P is connected to earth (R = 0), if the venous needle 13 becomes disconnected, there is no current flowing through the venous branch 10 and therefore detector 17 detects a voltage drop equal to zero as is the case when patient P is insulated. If the

arterial needle 12 becomes disconnected, there is a voltage drop in section 10a, which is a function of the impedance Z1 of the peristaltic pump and is therefore significant owing to the high value of impedance Z1.

When Z2 is negligible, disconnection of venous needle 13 is detected both when the patient is insulated (R infinite) and when he is connected to earth (R = 0), as preferential flow of current occurs along the portion of extracorporeal circuit 2 on the side of patient P.

In the embodiment of Fig. 2, there is no capacitive coupler 25 since point C coincides with point B, whereas point D is located close to the venous needle 13. In this case, detector 17 detects the change in voltage along a section 10b, which is a section of branch 10 between point B (i.e. C) and, essentially, the venous needle 13.

When the patient P is insulated (R infinite) and Z2 is high, the current circulates through conductors 19 and 20, a portion of the venous branch 10 and a portion of the arterial branch 8. Disconnection of one of the needles 12 and 13 has the effect that the voltage drop is cancelled along the section 10b and the patient P.

When the patient P is connected to earth (R = 0), a disconnection of the venous needle 13 causes the cancellation of the voltage drop as in the preceding case, whereas when the arterial needle 12 is disconnected, the voltage drop becomes a function of the impedance Z1 as in the preceding case.

When Z2 is negligible, the considerations relating to the variant in Fig. 1 apply, except that the greater length of section 10b relative to section 10a makes it possible to refer to high values dV, at equal current passing through the venous branch 10, and therefore the device 14 is more efficient, as it increases the difference between the value of the voltage drop dV determined by the condition with the venous needle 13 connected and the zero value of dV.

According to a variant that is not shown, again the capacitive coupler 26 is omitted and is replaced with a conductive bracelet, not shown, connected directly to one wrist of the patient P. The operation of the said variant that is not shown does not differ substantially from the variant in Fig. 2.

According to the variant in Fig. 3, capacitive coupling 21 to the arterial branch 8 is omitted, since generator 16 is connected to earth via conductor 19, and detector 17 is connected to the venous branch 10 via conductor 23 and the capacitive coupler 25 at point C and to the arterial branch 8 via conductor 24 and the capacitive coupler 26 at a point F between the peristaltic pump 9 and arterial needle 12.

In use, when the patient P is insulated (R infinite) and the impedance Z2 is high, the value dV of voltage drop along section 10c of the venous branch, section 8c of the arterial branch 8, and the cardiovascular system of the patient P is detected. Section 10c is between point C and arterial needle 13, whereas section 8c is between point F and venous needle 12. Disconnection of one of the needles 12 and 13 causes cancellation of the voltage drop.

When the patient P is connected to earth (R = 0), a disconnection of the venous needle 13 causes the cancellation of the voltage drop, whereas a disconnection of the arterial needle 12 does not cause any appreciable change in the voltage drop dV.

When the impedance Z2 is negligible, a low current will pass along section 10c, however section 10c along which the voltage drop dV is determined is relatively long and therefore a detection thereof is significant.

In practice, all the variants of the monitoring device 14 described with reference to the Figs. 1, 2 and 3 enable a reliable detection of the disconnection of the venous needle 13, since a disconnection of the venous needle 13 causes, both when the patient P is insulated (R infinite), and when the patient is connected to earth (R = 0), a significant change in the

value dV of voltage drop, in comparison with the situation in which the venous needle 13 is connected.

CLAIMS

1. Method for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood in a machine (1) comprising a treatment device (4) and an extracorporeal circuit (2) having an arterial branch (8) and a venous branch (10), the arterial branch (8) having a first end fitted with an arterial needle (12) to be inserted in the vascular system of the patient and a second end connected to an inlet of the treatment device (4), and the venous branch (10) having a first end connected to an outlet of the treatment device (4) and a second end fitted with an venous needle (13) to be inserted in the vascular system of the patient,
the method being characterized in that it comprises the steps of:

- generating a potential difference between a first point (B) of the venous branch (10) and a part of the machine (1);
- detecting the value (dV) of a quantity that correlates with the electric current along at least one section (10a; 10b; 10c) of the venous branch (10) between the first point (B) and the venous needle (13); and
- comparing the detected value (dV) with a reference range (I).

2. Method according to claim 1, characterized in that the first point (B) is located between the venous needle (13) and a bubble trap (11) connected to the venous branch (10).

3. Method according to claim 1, characterized in that the quantity that correlates with the current is a voltage drop.

4. Method according to claim 1, characterized in that it comprises the step of emitting at least one control signal (S, T, G) when the detected value (dV) is outside the reference range (I).

5. Method according to claims 2 and 3, characterized in that the voltage is generated by means of a generator (16) and detection is by means of a voltage drop detector (17), the generator (16) and the detector (17) being connected to the extracorporeal circuit (2) by means of capacitive couplers (21, 22, 25, 26).

6. Method according to claim 5, characterized in that a potential difference is generated between the first point (B) and the arterial branch (8) at a second point (A) located between the arterial needle (12) and a peristaltic pump (9) arranged on the arterial branch (8).

7. Method according to claim 6, characterized in that the voltage detector (17) is connected to the venous branch (10) at a third and fourth point (C, D) located between the first point (B) and the venous needle (13), the section (10a) of the venous branch (10) where the detection takes place being located between the third and fourth point (C, D).

8. Method according to claim 6, characterized in that the voltage detector (17) is connected to the venous branch (10) at a third point (C) coinciding with the first point (B) and at a fourth point (D) close to the venous needle (13), the section (10b) of the venous branch (10) where the detection takes place being located between the third point (C) and the venous needle (13).

9. Method according to claim 5, characterized in that a potential difference is generated between the first

point (B) and a part of the machine (1) connected to earth.

10. Method according to claim 9, characterized in that the voltage drop detector (17) is connected to the third point (C) and to the arterial branch (8) at a fifth point (F) located between the peristaltic pump (9) and the arterial needle (12), the section (10c) of the venous branch (10) where the detection takes place being located between the third point (C) and the venous needle (13).

11. Device for monitoring the access to the cardiovascular system of a patient undergoing an extracorporeal treatment of blood in a machine (1) comprising a treatment device (4) and an extracorporeal circuit (2) having an arterial branch (8) and a venous branch (10), the arterial branch (8) having a first end fitted with an arterial needle (12) to be inserted in the vascular system of the patient and a second end connected to an inlet of the treatment device (4), and the venous branch (10) having a first end connected to an outlet of the treatment device (4) and a second end fitted with an venous needle (13) to be inserted in the vascular system of the patient,
the device (14) being characterized in that it comprises:

- a voltage generator (16) for generating a potential difference between a first point (B) of the venous branch (8) and a part of the machine (1);
- a detector (17) for detecting the value (dV) of a quantity that correlates with the electric current along at least one section (10a; 10b; 10c) of the venous branch (10) between the first point (B) and the venous needle (13);
- calculating means (15) for comparing the detected value (dV) with a reference range (I).

12. Device according to claim 11, characterized in that the first point (B) is between the venous needle (13) and a bubble trap (11) arranged along the venous branch (10).

13. Device according to claim 11, characterized in that the detector (17) is a voltage drop detector (17).

14. Device according to one of the claims from 11 to 13, characterized in that the calculating means (14) is designed to emit at least one control signal (S, T, G) when the detected value (dV) is outside the reference range (I).

15. Device according to claims 12 and 13, characterized in that the generator (16) and the detector (17) are connected to the extracorporeal circuit (2) by means of capacitive couplers (21, 22, 25, 26).

16. Device according to claim 15, characterized in that each of the capacitive couplers (21, 22, 25, 26) comprises at least one metal tube (27) wound around a respective portion of the extracorporeal circuit (2).

17. Device according to claim 15, characterized in that the generator (16) is connected to the venous branch (10) at the first point (B) and to the arterial branch (8) at a second point (A) located between the arterial needle (12) and a peristaltic pump (9) arranged on the arterial branch (8).

18. Device according to claim 17, characterized in that the detector (17) is connected to the venous branch (10) at a third and fourth point (C, D) located between the first point (B) and the venous needle (13), the section (10a) of the venous branch (10) where the detection takes place being located between the third and fourth point (C, D).

19. Device according to claim 17, characterized in that the detector (17) is connected to the venous branch (10) at a third point (C) which coincides with the first point (B), and at a fourth point (D) which is located close to the venous needle (13), the section (10b) of the venous branch (10) where the detection takes place being located between the first point (B) and the venous needle (13).

20. Device according to claim 15, characterized in that the generator (16) is connected to the venous branch (10) at the first point (B) and to a part of the machine (1) connected to earth.

21. Device according to claim 20, characterized in that the detector (17) is connected to the venous branch (10) at a third point (C) and to the arterial branch (8) at a fourth point (F), the fourth point (F) being located between the peristaltic pump (9) and the arterial needle (12), the section (10c) of the venous branch (10) where the detection takes place being located between the third point (C) and the venous needle (13).

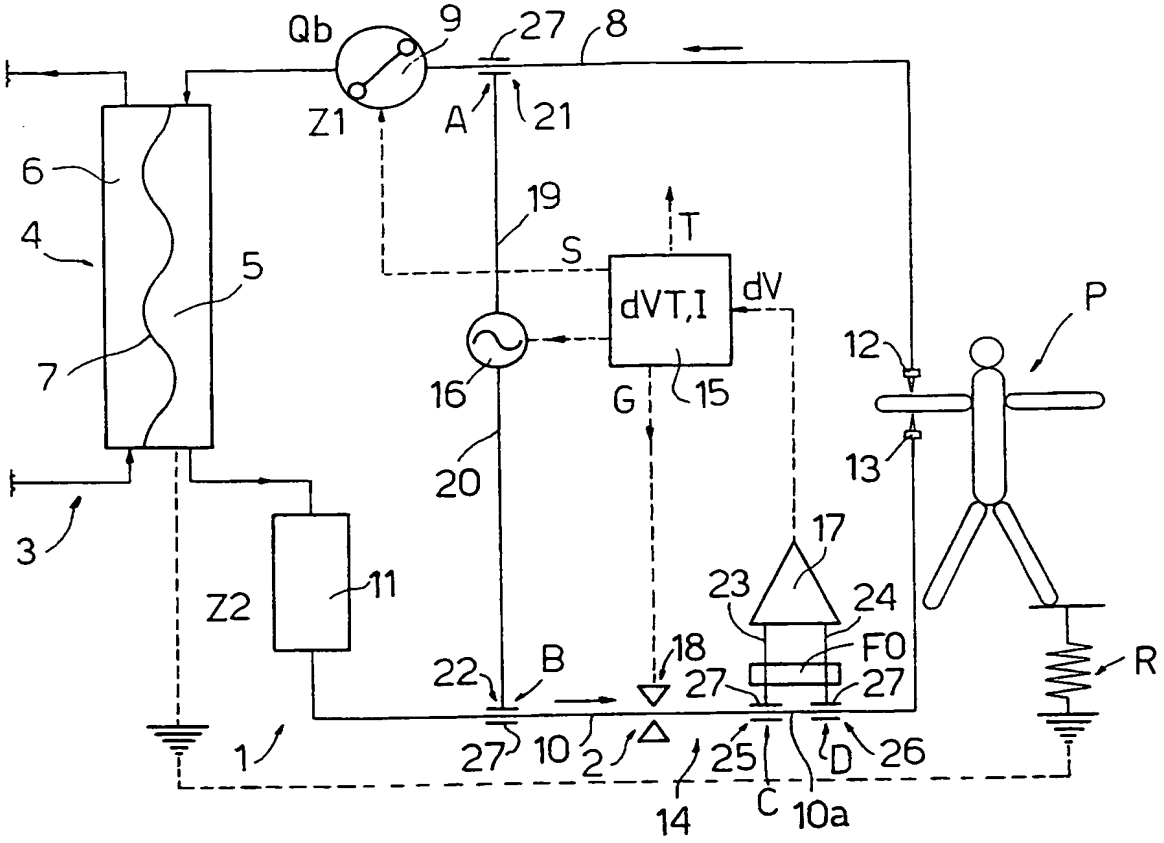
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Fig. 1

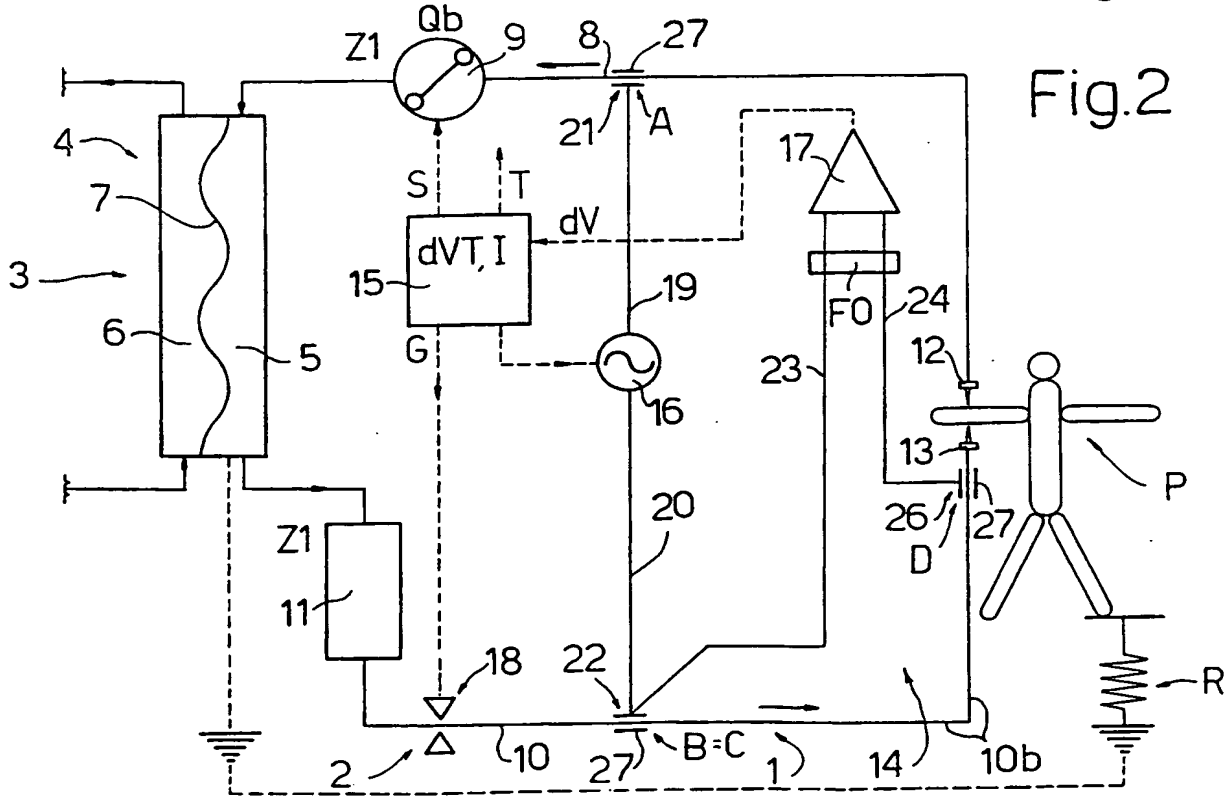
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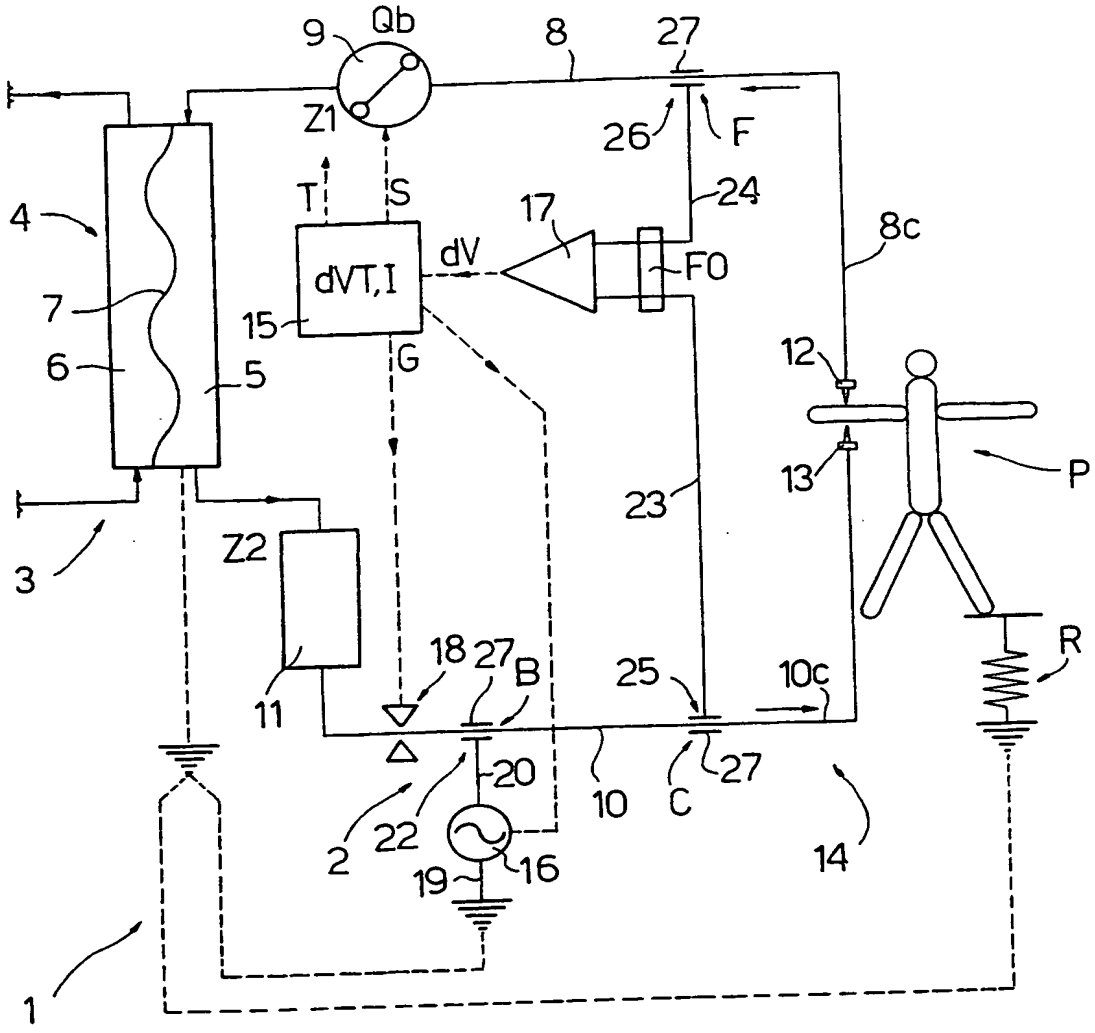
Fig. 2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1

Fig.3

INTERNATIONAL SEARCH REPORT

Intern[illegible]al Application No
PCT/IB 00/01954

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 12588 A (ENDER HELMUTH ;FRESENIUS MEDICAL CARE DE GMBH (DE)) 18 March 1999 (1999-03-18) cited in the application claims; figure	1,2,4, 11,12,14
A	FR 2 067 572 A (AURA) 20 August 1971 (1971-08-20) claim 1; figure 4	5,15
A	US 4 661 093 A (BECK WALTER ET AL) 28 April 1987 (1987-04-28) claims 1,6-8; figure 1	5,15
A	WO 99 24145 A (AKSYS LTD ;KJELLSTRAND CARL M (US)) 20 May 1999 (1999-05-20)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 May 2001	10/05/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 00/01954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9912588 A	18-03-1999	DE 19739099 C	28-01-1999
		AU 9623198 A	29-03-1999
		EP 1019118 A	19-07-2000
FR 2067572 A	20-08-1971	NONE	
US 4661093 A	28-04-1987	DE 3321151 A	13-12-1984
		AT 36242 T	15-08-1988
		DE 3473229 D	15-09-1988
		EP 0128388 A	19-12-1984
		JP 1709724 C	11-11-1992
		JP 3075184 B	29-11-1991
		JP 60007851 A	16-01-1985
		JP 1838924 C	25-04-1994
		JP 4261670 A	17-09-1992
		JP 5029469 B	30-04-1993
		US 4792328 A	20-12-1988
		US 4936834 A	26-06-1990
WO 9924145 A	20-05-1999	AU 9392798 A	31-05-1999

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
HP 1323		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IB 00/01954	22/12/2000	28/12/1999
Applicant		
HOSPAL AG et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 00/01954

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 12588 A (ENDER HELMUTH ;FRESENIUS MEDICAL CARE DE GMBH (DE)) 18 March 1999 (1999-03-18) cited in the application claims; figure	1,2,4, 11,12,14
A	FR 2 067 572 A (AURA) 20 August 1971 (1971-08-20) claim 1; figure 4	5,15
A	US 4 661 093 A (BECK WALTER ET AL) 28 April 1987 (1987-04-28) claims 1,6-8; figure 1	5,15
A	WO 99 24145 A (AKSYS LTD ;KJELLSTRAND CARL M (US)) 20 May 1999 (1999-05-20)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 00/01954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9912588 A	18-03-1999	DE 19739099 C	28-01-1999
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WO 9924145 A	20-05-1999	AU 9392798 A	31-05-1999

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PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference HP 1323	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IB 00/01954	International filing date *(day/month/year)* 22/12/2000	(Earliest) Priority Date *(day/month/year)* 28/12/1999
Applicant HOSPAL AG et al.		

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